September 21, 2005

To: Food and Drug Administration

Office of Management Programs

Division of Freedom of Information (HFI-35)

5600 Fishers Lane Rockville, MD 20857 fax: (301) 443-1726

From: Jeanne Sears, MS, RN

Department of Health Services University of Washington

Box 357660

Seattle, WA 98195 (425) 828-4241

jeannes@u.washington.edu

PARKING & INFORMATION OFC

Re: FOIA Request

We are requesting copies of all scientific studies and research data, including references to other supporting data or literature, that was submitted in support of supplement S020 for PMA # P860004. This is for the Medtronic SynchroMed programmable pump, specifically the added indication for pain of non-malignant origin approved in 1991.

We are willing to pay the fees specified for noncommercial use requestors.

Thank you very much,

Jeanne Sears

05-13211 RECEIVED

SEP 2 3 2005

FDA DFOI (HFI-35)

HF2-23